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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,958	08/07/2001	Lorenz Poellinger	3743/49008	9818

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,958	POELLINGER ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17 and 30, as specifically drawn to an isolated polypeptide comprising an amino acid of SEQ ID NO: 4 with various alterations to the residues, classified in class 530, subclass 350.

II. Claims 18, 19, 20, 22-29, as specifically drawn to host cell, wherein said host cell contains a vector comprised of an isolated nucleic acid molecule which encodes SEQ ID NO: 4, classified in class 435, subclass 320, 252.1; class 536, subclass 23.1.

III. Claim 21, 53-54, as specifically drawn to a pharmaceutical composition comprising a pharmaceutical acceptable carrier and an isolated polypeptide of the amino acid sequence of SEQ ID NO: 4 with an altered PYI motif or P564 spanning protein, classified in class 424, subclass 184.1.

IV. Claims 31-32, as specifically drawn to a method of making an isolated degradation box protein by introducing a nucleic acid of SEQ ID NO:2 into a host cell or cellular extract, classified in class 435, subclass 70.1.

V. Claims 33-36, 37-39, as specifically drawn to a method for screening for an agent which modulates N-TAD function, classified in class 435, subclass 4.

VI. Claims 33-36, 40-42, as specifically drawn to a method for screening for an antagonist of the PYI motif or P564 spanning protein which modulates N-TAD function, classified in class 435, subclass 4.

VII. Claim 43, 55, as specifically drawn to a method of regulating the function of a molecule by administering a substance, classified in class 424, subclass 184.1.
(Upon election of Group VII, applicant must further choose ONE molecule from those listed in Claim 55, as each molecule is a distinct invention, NOT a species)

VIII. Claims 44, 56, as specifically drawn to a method of regulating the function of a molecule by administering an antagonist, classified in class 424, subclass 184.1.
(Upon election of Group VIII, applicant must further choose ONE molecule from those listed in Claim 56, as each molecule is a distinct invention, NOT a species)

IX. Claims 45-47, as specifically drawn to a method of treating an ischemic condition by administering full length HIF-1 alpha with at least one modification of the PYI motif, classified in class 424, subclass 184.1.

X. Claims 48, as specifically drawn to a method of treating a disease by administering full length HIF-1 alpha with at least one modification of the PYI motif, classified in class 424, subclass 184.1.
(Upon election of Group X, applicant must further choose ONE disease from those listed in Claim 48, as each disease is a distinct invention, NOT a species)

XI. Claims 49-50, as specifically drawn to a method of treating an ischemic condition by administering an agonist of the PYI motif or P564 spanning protein, classified in class 424, subclass 184.1.

XII. Claims 51-52, as specifically drawn to a method of promoting conditions in an *in vitro* culture by adding a substance, classified in class 435, subclass 4.

(Upon election of Group XII, applicant must further choose ONE substance from those listed in Claim 51, as each substance is a distinct invention, NOT a species)

XIII. Claim 57, as specifically drawn to a method of effecting degradation of a molecule by administering a substance, classified in class 424, subclass 9.1.
(Upon election of Group XIII, applicant must further choose ONE molecule from those listed in Claim 57, as each molecule is a distinct invention, NOT a species)

XIV. Claims 58-59, as specifically drawn to a method of increasing or regulating angiogenesis by administering a HIF-1 alpha mutant having an alteration on at least one residue, classified in class 424, subclass 184.1.

XV. Claims 60-61, as specifically drawn to a method of regulating or increasing erythropoiesis by administering a HIF-1 alpha mutant having an alteration on at least one residue, classified in class 424, subclass 184.1.

XVI. Claims 62-63, as specifically drawn to a method of controlling oxygen-dependent degradation of a protein by incorporating SEQ ID NO: 5 in a cellular protein, classified in class 436, subclass 86.

XVII. Claims 64-66, as specifically drawn to a method of detecting an HIF-1 alpha sequence encoding an oxygen-independent HIF-1 alpha mutant by evaluating a sample sequence for an alteration to any one of residues 532 through 585, classified in class 436, subclass 86.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different

modes of operation, different functions and different effects. For example, Group I is drawn specifically to a isolated polypeptide comprising SEQ ID NO: 4, whereas Group II is specifically drawn to a nucleic acid, a vector and a host cell.

The invention of Groups IV-XVII are materially distinct methods of which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response variables, and criteria for success. For example, Group IV is drawn to a method of making a protein by introducing a nucleic acid into a host cell, whereas Group V is specifically drawn to a method of screening for an agent which modulates N-TAD function.

The invention of Groups I and the methods of Groups VI, X are related as product and process of using the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the isolated polypeptide can be used to in a materially different process such as a screening agent which modulates the a function or used as an agent for treatment of a disease.

The inventions of Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Group II is drawn to a vector, whereas Group III is drawn to a pharmaceutical composition both of which are not used in any of the methods described in Groups IV-XVI and cannot be used together, have different modes of operation, different functions, and different effects.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Species Election

Group I (Claims 1-17) is generic to a plurality of disclosed patentably distinct species comprising a variety of alterations to residues contained within SEQ ID NO 4 such as: PYI motif at 564-566 replaced by DDD or AAA, P564 replaced by A or H, ... altered FQL motif at 572-574.

Group IX, XI (Claims 47 and 50) is generic to a plurality of disclosed patentably distinct species comprising the number of ischemic conditions such as: brain infarction, heart infarction, and circulatory disorder, which differ in etiology, pathology and mechanism.

Groups XIV-XV (Claims 58-61) are generic to a plurality of disclosed patentably distinct species comprising a variety of HIF-1 alpha alterations such as: K547, P564, Y565... D571.

Group XVII (Claim 65) is generic to a plurality of disclosed patentably distinct species comprising a variety of HIF-1 alpha alterations such as: K547, P564, Y565, ... Q573, L574.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER